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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/526,822  | 03/04/2005  | Hiroyuki Asada       | 05136/HG            | 1106             |
| 1933 7590 06/09/2009<br>FRISHAUF, HOLTZ, GOODMAN & CHICK, PC<br>220 Fifth Avenue<br>16TH Floor<br>NEW YORK, NY 10001-7708 |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| FAY, ZOHREH A   |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 1612  |             |                      |                     |                  |
| MAIL DATE   |             | DELIVERY MODE        |                     |                  |
| 06/09/2009  |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/526,822

**Applicant(s)**

ASADA ET AL.

**Examiner**

ZOHREH A. FAY

**Art Unit**

1612

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4, 5 and 8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 5 and 8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 14, 2008 has been entered.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dean et al. (U.S. Patent 6,166,073) in view of The Patent Abstract of Japan and Helberg et al. (US 6,646,001).

Dean et al. teach the use of the claim-designated prostaglandin, latanoprost in an ophthalmic formulation in combination with benzalkonium chloride and polysorbate 80 at the claimed concentrations. See column 7, lines 15-20, column 7, lines 64-67, example 1 and claim 16. The above reference differs from the claimed invention in the presence of tonicity agents such as glycerin, propylene glycol, mannitol or sugar and the concentrations of latanoprost. The Patent Abstract of Japan teaches that the addition of glycerol, propylene glycol, mannitol and sugar to ophthalmic formulations as old and well known. Hellberg et al. teach the use of the prostaglandin analogs, encompassing latanoprost as one of the species at the concentration of between about 0.00003 to about 0.5 percent in an ophthalmic formulation for the treatment of glaucoma and ocular hypertension. See the abstract and column 8, lines 21-24. The above reference also teaches the use of latanoprost at the concentration of 0.005 specifically. See example 4. It would have been obvious to a person skilled in the art to use latanoprost at the claimed concentration, motivated by the teachings of Hellberg et al., that teaches the

use of latanoprost at the claimed concentration in an ophthalmic formulation as old and well known. Helberg et al. also teach the use of mannitol, one of the claimed tonicity enhancing agents. See example 2. It would have been obvious to a person skilled in the art to use benzalkonium chloride with any carbon chain length, considering that the prior art teaches the use of benzalkonium chloride in general in combination with latanoprost in an ophthalmic formulation.

One skilled in the art would have been motivated to combine the teachings of the above references, since one relates to the use of the claimed prostaglandin, latanoprost in combination with benzalkonium chloride and polysorbate 80 in an ophthalmic formulation, the other relates to the use of non-ionic tonicity agents in ophthalmic formulations as old, and the third one relates to the use of latanoprost at the claimed concentrations in ophthalmic formulations. The use of any benzalkonium chloride would have been obvious to a person skilled in the art, considering that Dean et al. teach the use of benzalkonium chloride in general in combination with latanoprost in an ophthalmic formulation. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 1, 4, 5 and 8 are properly rejected under 35 U.S.C. 103.

Applicant's arguments and remarks have been carefully considered, but are not deemed to be persuasive. Applicant alleges criticality to the lack of turbidity using the claimed benzalkonium chloride having 12 carbon atoms in comparison to the use of benzalkonium chloride by the prior art. It is the examiner's position that the presented data in the specification fail to demonstrate such advantage, considering that such data

do not compare a composition of latanoprost, the claimed benzalkonium chloride a tonicity enhancing agent with a composition of the same ingredient having the prior art benzalkonium chloride.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZOHREH A. FAY whose telephone number is (571)272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ZF  
/Zohreh A Fay/  
Primary Examiner, Art Unit 1612